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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,063	10/04/2004	James H Johnson	048777/283016	4270
826	7590	02/01/2006	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/510,063

Applicant(s)

JOHNSON ET AL.

Examiner

Niloofar Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-41 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 17-27 is/are rejected.
- 7) ☒ Claim(s) 14, 16 and 42-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 1-47 are pending.

2. ***Priority***

This application is a 371 of PCT/US03/10556, filed on 04/05/2003, which claims benefit of 60/370,252, filed on 04/05/2002.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5, 8, 11, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are rejected because "acid halide" has no antecedent basis nor does it have a definition in the base claim 1. Claim 8 is rejected because "pyridine" has no antecedent basis nor does it have a definition in the base claim 4. Claim 11 is rejected because " acid halide" has no antecedent basis nor does it have a definition in the basis claim 9. Correction is required.

Claim 27 is rejected because RN is undefined. What does RN mean? Does it mean  $R_n$ ? Correction is required.

4. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1625

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not describe in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks description for all the compounds to which are possibly acylated and to what final product would be. Claim 1 is drawn to all compounds would be acylated. There is no description to all the compounds to acylate. Therefore, the specification lacks description of "acylating a compound".

**5. Claim Rejections - 35 USC § 112**

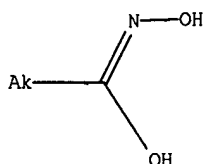
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

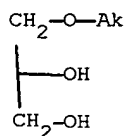
Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks enablement of the term "acylating a compound" which is claimed in the method claim. While enabling for paclitaxel molecules which are on page 26, table 2, and page 28, table 3 it is not seen where this is enabling for hydroximic acid, wherein



And glyceride, wherein



or other taxane molecules.

## 6. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 9-11, 15, 17, 19-27 are rejected under 35 U.S.C.

102(b) as being anticipated by Kingston et al. of US 5,411,984. Kingston disclosed on the Fig. 1 (making compound 3), Fig. 2 (making compound 5), Fig. 3 (making compound 8a), Fig. 4 (making compound 9a), Fig. 5

(making compound 10, Fig. 6 (making compound 6), Fig. 7 (making compound 14) the instant claimed process. Therefore, the instant claims are anticipated by Kingston et al.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al., Bioorganic & medicinal Chemistry Letters, Vol. 9, pages 1639-1644. Yamaguchi et al. disclosed on the Table 1, steps iii, iv the instant claimed process. Therefore, the instant claims are anticipated by Yamaguchi et al.

8. Claims 1-7, 9-13, 15, 17, 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Groot et al., J. Med. Chem, Vol. 43, pages 3093-3102. Groot et al. disclosed on Scheme 2 the instant claimed process. Therefore, the instant claims are anticipated by Groot et al.

9. Claims 1-3, 6-7, 9-11, 15, 17, 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenwald et al., J. Org. Chem, Vol. 60, pages 331-336. Greenwald et al. disclosed on Figure 1 (process to make compound 2a), Figure 2 (the process to make compound 2b) and page 335, 2<sup>nd</sup> column, lines 4-10, wherein diisopropylethylamine is in solution, the instant claimed process. Therefore, the instant claims are anticipated by Greenwald et al.

10. Claims 1-2, 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Golik et al., Bioorganic & Medicinal Chemistry Letters, Vol. 6, pages 1837-1842. Golik et al. disclosed on page 1839, lines 6, 14-16

the instant claimed process. Therefore, the instant claims are anticipated by Golik et al.

**11. Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-23 are rejected under 103(a) as being unpatentable over Kingston et al. of US 5,411,984 in view of Yamaguchi et al., Bioorganic & medicinal Chemistry Letters, Vol. 9, pages 1639-1644.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kingston et al. on Fig. 1 (making compound 3), Fig. 2 (making compound 5), Fig. 3 (making compound 8a), Fig. 4 (making compound 9a),

Fig. 5 (making compound 10, Fig. 6 (making compound 6), Fig. 7 (making compound 14) disclosed analogous process.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the prior art process does not teach THF as a solvent. The Yamaguchi et al. teaches the analogues process with the THF as a solvent.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of Kingston et al. with a conventional alternative conversion step by adding THF as a solvent to obtain the instant process.

12. Claims 18-23 are rejected under 103(a) as being unpatentable over Greenwald et al., J. Org. Chem, Vol. 60, pages 331-336. in view of Yamaguchi et al., Bioorganic & medicinal Chemistry Letters, Vol. 9, pages 1639-1644.

Determination of the scope and content of the prior art (MPEP §2141.01)

Greenwald et al. on Figure 1 (process to make compound 2a), Figure 2 (the process to make compound 2b) and page 335, 2<sup>nd</sup> column, lines 4-10 disclosed analogous process.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the prior art process does not teach THF as a solvent. The



Yamaguchi et al. teaches the analogues process with the THF as a solvent.

*Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)*

One having ordinary skill in the art would be motivated to modify the process of Greenwald et al. with a conventional alternative conversion step by adding THF as a solvent to obtain the instant process.

**13. *Claim Objections***

Claims 14, 16, 42-47 are objected to as dependent upon rejected base claims 1, 9, and 28, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

**14. *Allowable Subject Matter***

The closest prior art for claims 28-41 is US 5,411,984. The difference is that the prior art has pyridine as a hindered base instead of 2,6-lutidine or N ethyldicyclohexylamine. Therefore, the claims are free of prior art.

**15.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

NILOOFAR RAHMANI

01/25/2006

NR

  
MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625